carecentrix

Provider Newsflash
April 2023

FDA Recall – Philips Respironics Reworked DreamStation CPAP, BiPAP Machines

Purpose of this communication:

- We are writing to inform you that effective immediately the FDA has issued a Class 1 recall notice of certain reworked Philips Respironics DreamStation CPAP, BiPAP machines distributed from December 1, 2021 to October 31, 2022 due to the risk they may deliver inaccurate or insufficient therapy. Certain reworked Philips DreamStations were assigned incorrect or duplicate serial numbers during initial programming. This duplication can cause therapy to be delivered using the wrong prescription or factory default settings. Additionally, the devices may fail to deliver any therapy at all with no warning or indication to the user that the device is not working the way the doctor intended or prescribed.
- Product Models: REP DreamStation Auto CPAP Recert, DreamStation Auto, FR REP DreamStation Auto BiPAP, DOM-RECRT, and REP DreamStation Auto CPAP, DOM - RECRT

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-reworked-dreamstation-cpap-bipap-machines-risk-they-may-deliver?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.